

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Monday, August 18, 2008, 10:00 am – 11:00 am ET

Minutes

I. Welcome and Introductions - call participants (listed alphabetically):

- Joan Berger, Image Solutions, Inc.
- Cheryl Blik, Teva Pharmaceuticals USA
- Terry Brunone, GlaxoSmithKline Consumer Healthcare (SPL process team co-leader)
- Chris Guay, The Procter & Gamble Company
- John Lorenc, Reed Technology & Information Services, Inc.
- Paula Markert, GlaxoSmithKline Consumer Healthcare (co-leader)
- Andras Megyeri, Novartis Consumer Health, Inc.
- Kathryn Moreng, Bayer Consumer HealthCare
- Devon Morgan, Perrigo Company (co-leader)
- Priscilla Mott, McNeil Consumer Healthcare
- Janet Riffitts, McNeil Consumer Healthcare
- Gary Saner, Reed Technology & Information Services, Inc.
- Barbara Spallitta, Reckitt Benckiser, Inc.
- Craig Trautman, Intagras
- Marcia Howard, CHPA staff (sub-team liaison)

II. Standing Teleconference Date and Time

It was agreed that the standing calls would remain on Mondays but will be held at 1:00 pm ET instead of 10:00 am ET as originally scheduled.

III. Draft Guidance

Feedback on the draft guidance should be sent sub-team leaders Paula Markert and Devon Morgan, and Marcia Howard by Friday, August 22, 2008. The draft guidance can be viewed at: [http://www.fda.gov/cder/guidance/OC2008145\(2\).pdf](http://www.fda.gov/cder/guidance/OC2008145(2).pdf). The corresponding *Federal Register* notice is available at: <http://edocket.access.gpo.gov/2008/pdf/E8-15801.pdf>.

Currently the only feedback on the draft is that non-substances will only be listed in text format and will no longer be included under product listing. It will be assumed that there are no additional comments, questions, or concerns if no additional

IV. Question-and-Answer/Recommendations for SPL OTC issues

A question-and-answer document will be created based on input from sub-team members. The document will be circulated and posted on the SPL Wiki website (currently under development) for members to provide answers (if known) and feedback on the issues. Questions and concerns that cannot be addressed by OTC sub-team members or others working on the SPL project will be periodically forwarded to FDA for input. Sub-team members are encouraged to submit any SPL questions or recommendations to Markert, Morgan, and Howard at their convenience.

[Theresa \(Terry\) Brunone](#), leader of the SPL Process Team, noted that the SPL OTC sub-team will have access to materials from the other sub-teams via the Wiki page. There are several other SPL sub-teams working on various aspects of SPL: Technical, Process Communication, Generics, Veterinary Medicine, Biologics, Device, and Drug Listing/Electronic Registration. Brunone noted that OTCs are amongst the last group to be affected by the SPL project but it is good that the sub-team is active now because the **effective date will be June 1, 2009**.

Brunone also provided the following websites as background information.

- SPL Guidance and Supporting Documents (from <http://www.fda.gov/oc/datacouncil/spl.html>) – **Note:** updates may be available for some documents so please check datacouncil website for more information.

- [Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing \(Draft\)](#)
- Structured Product Labeling Implementation Guide for FDA Drug Establishment Registration and Drug Listing v1.0 (updated July 10, 2008) [PDF](#)
- Structured Product Labeling Validation Procedures for Drug Establishment Registration and Drug Listing v1.0 [PDF](#)
- Instructions for using Electronic Drug Establishment Registration and Drug Listing XForms v1.0 [PDF](#)
- The Electronic Submission Gateway resources page:
<http://www.fda.gov/esg/ESG/default.htm>
- Vendor list: <http://spl-work-group.wikispaces.com/Vendors> (Note: **NO** endorsement or recommendation of any vendor is implied or intended.)

V. Upcoming SPL Educational Forums

- a. Drug Information Association (DIA) Webinar (September 9, 2008)
- b. DIA In-person workshop (tentatively scheduled for October 29-30, 2008, in Philadelphia, PA)
- c. Generic Pharmaceuticals Association (GPhA) [Fall Technical Workshop](#) October 28, 2008, in Rockville, MD [prior to the Fall Technical Conference in Washington, DC (October 29-30)]

VI. Other

Sub-team members were alerted to the pilot program currently available through FDA to ease into electronic submissions (see announcement of pilot program sent as attachment to email). Companies were encouraged to use this time to help identify potential issues with electronic submissions prior to the June 1, 2009, implementation date.

Companies should be aware of the following if they do decide to participate in the pilot:

- 1) Once a submission is completed electronically, you cannot return to paper submissions for future submissions.
- 2) The submission should be sent only in electronic format (*i.e.*, no paper submission of the same information).
- 3) The electronic submission gateway should *not* be used for test submissions as it is for “true” electronic submissions only. If companies want to conduct a test submission, please do so using SPL@fda.hhs.gov.
- 4) Labeler codes and site registrations must be entered electronically *prior* to completing electronic drug listings.

Sub-team members are encouraged to have external and internal colleagues who may be involved with (or should be informed about) SPL to invite them to participate on the SPL OTC sub-team.

VII. Next steps and Assignments

- A. Sub-team members should provide feedback on draft guidance by August 22, 2008.
- B. Marcia Howard will send updated teleconference invitations for new time [completed].

MDH/08-19-08

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Last Revised: August 20, 2008 Sent: August 20, 2008